DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-03-43

August 27, 2003

Michael E. Schnurbusch, Owner
M.B! Seafood Company, Inc.
650 Azalea Avenue
Merritt Island, Florida 32952

Dear Mr. Schnurbusch:

On April 23 and 24, 2003, FDA inspected your seafood processing facility, located at the above address. We found that you have serious deviations from the Seafood HACCP Regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123) and the Current Good Manufacturing Practice Regulation for Manufacturing, Packing, or Holding Human Food (CGMP), Part 110 (21 CFR 110). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly, your ready-to-eat products including smoked fish, fish dip and crabmeat; and, Scombrotoxin (histamine) forming fresh fish are adulterated in that these products have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. You can find the Act, the seafood HACCP regulation, and the CGMP regulations through links in FDA's homepage at http:// www.fda.gov.

The deviations, observed during the inspection and upon further examination of the documents collected during that inspection, are as follows:

1. You must implement the record keeping system that you listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations for adequacy of ice at the Receiving critical control point to control histamine formation listed in your HACCP plan for "Tuna &, Mahi & Sword & Snapper."

2. You must have a HACCP plan that, at a minimum, lists the critical limits that must be met, to comply with 21 CFR 123.6 (c) (3). A critical limit is defined in 21 CFR 123.3(c) as "the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard."

a.) However, your firm's HACCP plan for "Ready-To-Eat" products including smoked fish, fish dip, and crabmeat lists a critical limit at the Receiving and Cooler Storage critical control points that is not adequate to control pathogen growth/toxin formation as a result of time/temperature abuse.

b.) However, your firm's HACCP plan for "Tuna & Mahi & Sword & Snapper" lists a critical limit at the Receiving and Cooler Storage critical control points that is not adequate to control histamine formation as a result of time/temperature abuse. Moreover, the critical limit of [redacted]F as listed in your HACCP plans for "Ready-To-Eat" products and for "Tuna & Mahi & Sword & Snapper" is not adequate. FDA recommends that microbiologically sensitive products and histamine forming products should be received and stored at a temperature of 40°F or less, and that there is continuous temperature control, including during transit.

c.) However, your firm's revised HACCP plan for "Rainbow Trout, Cobia, Grouper, Salmon, Mahi, and Wahoo," dated April 28, 2003, does not list an adequate critical limit to control parasites. The critical limit is based on controlling temperature at 40°F; however, parasites can survive this temperature. FDA recommends control of parasites by freezing. The length of time needed to control the parasites is dependant on the temperature at which your product is frozen. You may wish to consult Chapter 5 of the Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001 for specific guidance.

3. Since you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate, to comply with 21 CFR 123.7(b). However, your corrective action plan at the Receiving and Cooler Storage critical control points in your HACCP plans for "Ready-To-Eat" products including smoked fish, fish dip, and crabmeat, and "Tuna & Mahi & Sword & Snapper" are not appropriate. Your corrective action should not only describe how you will prevent abused product from reaching the consumer once a critical limit has been exceeded (you list "reject" or "check product if temp over [redacted]F reject"), but should also describe how you will regain control of your operation. Possible methods of regaining control of your operation include: moving product to a lower temperature cooler; repairing the defective cooler; or, immediately adding ice to the affected product.

We may take further action, if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You should include in your response documentation such as monitoring records, revised HACCP plans, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that

you will explain the reason for your delay and state when you will correct the remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP Regulation, and the Current Good Manufacturing Practices Regulations for Human Food (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Diane J. Englund, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida, 32751. If you have questions regarding any issue in this letter, please contact Ms. Englund at (407) 475-4741.

Sincerely,

Emma R. Singleton
District Director
Florida District